

Applicants : David M. Stern, et al.
U.S. Serial No: 09/872,185
Filed : June 1, 2001
Page 2

REMARKS

Claims 3, 7-13 and 16-18 are pending and under examination. No claim has been added, canceled, or amended herein. Accordingly, claims 3 and 7-18 are still pending and under examination.

Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 3 and 7-11 under 35 U.S.C. §103(a) as allegedly obvious over United States Patent No. 5,864,018 ("Morser") in view of Ritthauer et al. (Amer. J. Path., 146(3):668-694, 1995) ("Ritthauer").

Specifically, the Examiner asserts that it would have been prima facie obvious at the time of the invention to treat inflammation in a subject by inhibiting the interaction of AGE and RAGE by administering sRAGE or the anti-RAGE antibodies disclosed by Morser, because Morser demonstrates that sRAGE or anti-RAGE antibodies block the interaction between RAGE and its ligands and Ritthauer teaches that RAGE and its ligands are involved in the diseases involving inflammation.

In response to the Examiner's rejection of claims 3 and 7-11, applicants respectfully traverse. In order to find the claims obvious over Morser in view of Ritthauer, the prior art references, in combination, must teach or suggest all the elements thereof, and create both a motive to combine and a reasonable expectation of success. Morser and Ritthauer fail to do this.

Applicants : David M. Stern, et al.
U.S. Serial No: 09/872,185
Filed : June 1, 2001
Page 3

Claims 3 and 7-11 provide a method for treating inflammation in a subject which comprises administering to the subject an agent selected from the group consisting of soluble receptor for advanced glycation endproduct (sRAGE) or anti-RAGE antibody or anti-EN-RAGE F(ab')₂ fragment in an amount which inhibits the interaction between receptor for advanced glycation endproduct (RAGE) and either AGE or EN-RAGE, thereby treating inflammation in the subject.

Applicants maintain that Morser, in view of Ritthauer, fails to create a reasonable expectation of success.

According to M.P.E.P. §2143.02, lack of predictability can serve as evidence that no reasonable expectation of success exists. Applicants note that their surprising discovery that inhibiting the interaction of RAGE and either AGE or EN-RAGE is useful in treating inflammation, and maintain that this discovery could not have been predicted from Morser, in view of Ritthauer, because of the unpredictability of living systems. Without knowledge of applicants' experimental data in this application, one of ordinary skill would have no reasonable expectation that inhibiting the interaction of RAGE and either AGE or EN-RAGE would succeed in treating inflammation. The Examiner's assertion of obviousness ignores this point.

Rather, the Examiner has applied an "obvious to try" rationale in support of the obviousness rejection. This rationale, which applicants do not concede exists, is inadequate support for an obviousness rejection. (*O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988))

Applicants : David M. Stern, et al.
U.S. Serial No: 09/872,185
Filed : June 1, 2001
Page 4

Accordingly, applicants maintain that the subject claims are not obvious over Morser in view Ritthauer and therefore satisfy the requirements of 35 U.S.C. §103(a).

Further, the Examiner rejected claims 12, 13 and 16-18 under 35 U.S.C. §103(a) as allegedly obvious over Morser and Ritthauer in view of United States Patent No. 5,998,408 ("Baker").

Specifically, the Examiner asserts that it would have been prima facie obvious at the time of the invention to treat inflammation associated with autoimmune disease in a subject by inhibiting the interaction of AGE and RAGE by administering sRAGE or the anti-RAGE antibodies disclosed by Morser. This allegedly is because Morser demonstrates that sRAGE or anti-RAGE antibodies block the interaction between RAGE and its ligands, Ritthauer teaches that RAGE and its ligands are involved in the diseases involving inflammation and Baker teaches diseases involving inflammation, specifically the autoimmune process.

In response to the Examiner's rejection of claims 12, 13 and 16-18, applicants respectfully traverse the rejection of these claims.

Claims 12, 13 and 16-18 are dependant on claim 3 which is discussed above.

The non-obviousness of the rejected claims over Morser and Ritthauer is discussed above. Baker, which according to the Examiner merely teaches diseases involving inflammation, does not

Applicants : David M. Stern, et al.
U.S. Serial No: 09/872,185
Filed : June 1, 2001
Page 5

cure the deficiency of the other two references, in that it does not overcome the Examiner's failure to demonstrate the existence of a reasonable expectation of success.

Accordingly, applicants maintain that the subject claims are not obvious over Morser and Ritthauer in view of Baker, and therefore satisfy the requirements of 35 U.S.C. §103(a).

Obviousness-Type Double Patenting Rejection

The Examiner provisionally rejected claims 3-11 and 16 as allegedly unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 47, 50, 55-60, 62-65 and 67 of copending U.S. Application No. 09/167,705 in view of United States Patent No. 5,864,018 and Ritthauer et al. (1995). According to the Examiner, a timely filed terminal disclaimer in compliance with 37 C.F.R. §1.321(c) may be used to overcome a provisional rejection based on a nonstatutory double patenting ground.

In response, but without conceding the correctness of the Examiner's rejection, applicants will consider submitting a terminal disclaimer for claims 3-11 and 16 once the rejection is no longer provisional.

Summary

For the reasons set forth hereinabove, applicants respectfully request that all the claims of this application be allowed, and that the application proceed to issuance.

Applicants : David M. Stern, et al.
U.S. Serial No: 09/872,185
Filed : June 1, 2001
Page 6

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Alan J. Morrison
Reg. No. 37,399

Date

12/14/07

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
Tel. No. (212) 278-0400